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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,042	07/09/2003	Alonzo C. Aylsworth	2230-00100	4840

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CONLEY ROSE, P.C.
P. O. BOX 3267
HOUSTON, TX 77253-3267

EXAMINER	
LEWIS, AARON J	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,042	AYLSWORTH ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *35-39* is/are allowed.

6)☒ Claim(s) *1-30,32,33 and 40-55* is/are rejected.

7)☒ Claim(s) *31,34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 6-9,11-15,19-22,30,32,40-42,47-50,54 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonald, Jr. ('222).

As to claim 6, McDonald, Jr. (col.7, lines 25-40) discloses a method comprising: measuring (24) at least a portion of an airflow through a first naris to create a first measured airflow; and measuring (26) at least a portion of an airflow through a second naris to create a second measured airflow; wherein measuring at least a portion of the airflow through the first naris is accomplished without blocking the second naris; and wherein measuring at least a portion of the airflow through the second naris is accomplished without blocking the first naris (see col.6, lines 12-17 which discloses positioning sensors 24 and 26 adjacent a patient's nostrils and seefigs.1 and 3).

As to claims 7 and 8, McDonald, Jr. discloses the measuring steps taking place during inhalation and exhalation (col.1, lines 32-37).

As to claim 9, McDonald, Jr. discloses positioning sensors (24,26) adjacent a patient's nostrils in the path of nasal respiration (col.6, lines 12-17). In order for sensors 24 and 26 to be responsive to nasal respiration they must be placed within the path of

inhaled/exhaled air sufficiently close (i.e. at some known distance) to the nostril openings to function.

As to claim 11, McDonald, Jr. (col.7, lines 35-40) discloses the production of separate outputs indicative of the respiration sensed by the individual ones of the sensor elements. In the event that the sensed flow from one sensor is not equal to the other, monitor 14 will produce different separate outputs. Thus it is inherent that a difference is determined in the first and second measured airflows.

As to claim 12, McDonald, Jr. as discussed above with respect to claim 6 also discloses measuring pressure associated with first and second nares (col.3, lines 49-52).

As to claim 13, McDonald, Jr. discloses measuring a pressure proximate to an opening of each of the first and second naris (col.6, lines 12-17).

As to claim 14, McDonald, Jr. (col.7, lines 35-40) discloses the production of separate outputs indicative of the respiration sensed by the individual ones of the sensor elements. In the event that the sensed flow from one sensor is not equal to the other, monitor 14 will produce different separate outputs. Thus it is inherent that a difference is determined in the first and second measured airflows.

As to claim 15, McDonald, Jr. discloses the measuring steps taking place during inhalation and exhalation (col.1, lines 32-37).

As to claim 19, McDonald, Jr. as discussed above with respect to claim 6 also discloses a processor (14) electrically coupled to the first and second airflow sensors (24,26), and wherein the processor is programmed to substantially simultaneously read

the first and second measured flow signals (col.3, lines 55-57; col.7, lines 8-15 and lines 35-40).

As to claim 20, McDonald, Jr. as discussed above with respect to claim 6 also disclose a third airflow sensor (28) coupled to the processor (14), the third airflow sensor detects at least a portion of oral airflow to create and measured oral flow signal; and wherein the processor is programmed to substantially simultaneously read the first measured flow signal, the second measured flow signal, and the measured oral flow signal (col.3, lines 55-57; col.7, lines 8-15 and lines 35-40).

As to claim 21, McDonald, Jr. (col.7, lines 35-40) discloses the production of separate outputs indicative of the respiration sensed by the individual ones of the sensor elements. In the event that the sensed flow from one sensor is not equal to the other, monitor 14 will produce different separate outputs. Thus it is inherent that a difference is determined in the first and second measured airflows. As to the recited "programmed to determine", McDonald, Jr. (col.7, line 9) disclose the processor being "constructed" to interpret the sensed signals. Such "construction", given the electrical signal processing (interpretation) of the sensed airflow, inherently includes some processing albeit hard wired or software.

As to claim 22, McDonald, Jr. discloses monitor (14) which also includes a display device.

As to claim 30, McDonald, Jr. discloses a third airflow sensor (28) fluidly coupled to the first airflow sensor (i.e. in the case of moisture and/or pressure sensitive elements being employed as disclosed at col.3, lines 49-52), and wherein the first airflow sensor

produces the measured flow signal during inhalation, and wherein the third air flow sensor produces a measured flow during exhalation. It is noted that all three sensors produce measured flow signals during patient respiration which includes inhalation and exhalation.

As to claim 32, McDonald, Jr. (col.3, lines 49-52 in the case of a pressure sensitive elements) as discussed above with respect to claim 6 also discloses a differential pressure measurement device having first and second ports (24,25) and an indicator (14) coupled to the differential pressure measurement device, and wherein the indicator displays an indication of a difference in air pressure associated with airflow in each of the first and second nostrils. McDonald, Jr. (col.7, lines 35-40) discloses the production of separate outputs indicative of the respiration sensed by the individual ones of the sensor elements. In the event that the sensed flow from one sensor is not equal to the other, monitor 14 will produce different separate outputs. Thus it is inherent that a difference between the first and second measured airflows is indicated.

As to claim 40, McDonald, Jr. as discussed above with respect to claim 6 also discloses first and second pressure sensors (col.3, lines 49-52).

As to claims 41-42, McDonald, Jr. (col.7, lines 35-40) discloses the production of separate outputs indicative of the respiration sensed by the individual ones of the sensor elements. In the event that the sensed flow from one sensor is not equal to the other, monitor 14 will produce different separate outputs. Thus it is inherent that a difference between the first and second measured airflows is indicated.

As to claims 47-49, McDonald, Jr. as discussed above with respect to claim 6 also disclose a third airflow sensor (28) coupled to the processor (14), the third airflow sensor detects at least a portion of oral airflow to create and measured oral flow signal; and wherein the processor is programmed to substantially simultaneously read the first measured flow signal, the second measured flow signal, and the measured oral flow signal (col.3, lines 55-57; col.7, lines 8-15 and lines 35-40).

Claims 50 and 54 are substantially equivalent in scope to claim 6 and claim 52 is substantially equivalent in scope to claim 7 and are anticipated by McDonald, Jr. for the reasons set forth above with respect to claims 6 and 7.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 10,16,26-29,46,55 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald, Jr. ('222) in view of Derrick ('491).

The difference between McDonald, Jr. and claim 10 is measuring the airflow through a sensing tube of a bifurcated nasal cannula worn by a patient.

Derrick, in a method for measuring nasal and oral airflows, teaches measuring the airflow through a sensing tube of a bifurcated nasal cannula worn by a patient (figs.1 and 2) for the purpose of providing such a patient with breathable gases while analyzing respired gases (col.4, lines 8-9) in order to permit constant monitoring of patient

breathing thereby enabling prompt effective detection of apnea, choking and regurgitation of such a patient (col.5, lines 11-20).

It would have been obvious to modify McDonald, Jr. to measure nasal airflows through a bifurcated nasal cannula because it would have provided breathable gases to a patient while analyzing respired gases in order to permit constant monitoring of patient breathing thereby enabling prompt effective detection of apnea, choking and regurgitation of such a patient as taught by Derrick.

Claim 16 is substantially equivalent in scope to claim 10 and is included in McDonald, Jr. as modified by Derrick for the reasons set forth above with respect to claim 10.

As to claim 26, McDonald, Jr. as modified by Derrick (col.5, lines 49-55) teaches a bifurcated nasal cannula having a first sensing tube and a second sensing tube; and wherein the first sensing tube fluidly couples to the first airflow sensor, and wherein the second sensing tube fluidly couples to the second airflow sensor.

As to claim 27, McDonald, Jr. as modified by Derrick (col.5, lines 49-55) discloses the first sensing tube has an opening positioned within the airflow of the first naris.

As to claim 28, McDonald, Jr. discloses positioning the opening of the sensing tube proximate to an entrance of the first naris (col.6, lines 12-17).

As to claim 29, Derrick teaches the opening of the sensing tube is a measurable distance to an entrance to the first naris (col.5, lines 35-38).

As to claim 46, McDonald, Jr. as modified by Derrick (col.5, lines 49-55) teaches a bifurcated nasal cannula having a first sensing tube and a second sensing tube; and

wherein the first sensing tube fluidly couples to the first airflow sensor, and wherein the second sensing tube fluidly couples to the second airflow sensor.

Claim 55 is substantially equivalent in scope to claim 10 and is included in McDonald, Jr. as modified by Derrick for the reasons set forth above with respect to claim 10.

5. Claims 23,24,33,43,44,51,53 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald, Jr. ('222).

As to claims 23 and 24, McDonald, Jr. discloses a display device (14). While McDonald, Jr. is silent as to the particular configuration of the displayed information, it is submitted that the manner or configuration of displayed information can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular configuration including one having graphical information or one having difference information. Inasmuch as the display device (14) of McDonald, Jr. is disclosed as being "constructed" (e.g. programmed either hard wired or with software) to interpret sensed information (col.7, lines 8-11), it is fully capable of providing the recited function of displaying information graphically as well as displaying difference information.

Claims 33,43,44 are substantially equivalent in scope to claim 23 and is included in McDonald, Jr. for the reasons set forth above with respect to claim 23.

As to claims 51 and 53, McDonald, Jr. discloses the sensors being a temperature, pressure or moisture sensor (col.3, lines 49-52) and also discloses that the sensors may be a variety of sensors. It would have been obvious to employ any sensor known to

sense patient respiration including a mass flow sensor as an obvious matter of design choice with no new or unobvious results accruing. The particular sensor can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular sensor including a mass flow sensor. It is submitted that the sensors disclosed by McDonald, Jr. would have performed the airflow measurement as well as a mass flow sensor.

6. Claims 25,45 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald, Jr. ('222) in view of Karakasoglu et al. ('955).

The difference between McDonald, Jr. and claim 25 is a non-volatile memory coupled to the processor; and wherein the processor is programmed to store the first and second measured flow signals as a first set of data in the non-volatile memory, and wherein the processor is further programmed to analyze differences between the first set of data in the non-volatile memory and a second set of data taken at a different time.

Karakasoglu et al. (fig.5 and col.9, lines 7-14 and lines 58-67-col.10, line 42), in a nasal function test device, teach a non-volatile memory coupled to the processor; and wherein the processor is programmed to store the first and second measured flow signals as a first set of data in the non-volatile memory, and wherein the processor is further programmed to analyze differences between the first set of data in the non-volatile memory and a second set of data taken at a different time for the purpose of determining whether any of the sensed airflows are indicative of abnormal breathing (e.g. sleep apnea).

It would have been obvious to modify the processor (14) of McDonald, Jr. to include a non-volatile memory and to compare sensed airflows with stored airflows because it would have enabled the determination of whether any of the sensed airflows are indicative of abnormal breathing (e.g. sleep apnea) as taught by Karakasoglu et al..

Claim 45 is substantially equivalent in scope to claim 25 and is included in McDonald, Jr. as modified by Karakasoglu et al. for the reasons set forth above with respect to claim 25.

Allowable Subject Matter

7. Claims 31,34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 35-39 are allowed.

Conclusion

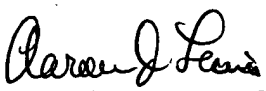
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant methods and devices for measuring a patient's respiratory airflow.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
September 21, 2005